TANBead® Nucleic Acid Extraction Kit

Fungi DNA Auto Plate

(For use with the Maelstrom 8 series and Maelstrom 4800 series)

CE IVD

M61FA46

(For Professional Use Only) V1

1. Intended Purpose

The TANBead® Nucleic Acid Extraction Kit is a nucleic acid purification kit based on magnetic bead technology by using with corresponding TANBead® Nucleic Acid Extractor, which can automatically extract nucleic acids from wide ranges of Fungi samples such as the yeast and filamentous fungi. Fungi specimens are pre-treated with glass beads first them processed through a series of automatic extraction steps and the high-quality nucleic acids can be used with any downstream application employing PCR-based qualitative, semi-quantitative and quantitative assays. The kit is intended for use by technicians, physicians, and biologists with well-trained in molecular biological techniques, the techniques of magnetic bead purification and in vitro diagnostic procedures. Any diagnostic results generated by using the sample preparation procedure in conjunction with any downstream diagnostic assay should be interpreted related to other clinical or laboratory findings. The kit is not limited to any specific disorder, condition, or other additional accompanying diagnostics. It is applicable for all population.

2. The basic principle

The silicon dioxide layer coated on the magnetic beads can adsorb the negatively charged molecules to purify nucleic acids from samples.

3. Specification

Starting Materials	Fungi specimen (OD_{600}= 1.0)
Elution Volume	90~130 µL
Typical DNA yield	1 µg
Typical A260 / A280	≥1.7

4. Component Supplied with the Kit

96

Auto Plate	6	Auto Plate with reagent buffers
Lysis Buffer	90 mL x 1	Guanidine salt, Tris buffer, surfactants
Elution Buffer	20 mL x 1	Nuclease-Free Water
Spin tips	96 tips	Spin tip assembled box
Protocol	1	Instruction guide for user

5. Auto Plate Content

Well	Buffer	Volume (µL)
1 / 7	-	-
2 / 8	Washing Buffer 1	800
3 / 9	Magnetic Beads	800
4 / 10	Washing Buffer 2	800
5 / 11	Washing Buffer 2	800
6 / 12	Elution Buffer	80

6. Kit Storage and Shelf Life

1) Components under room temperature (15~35°C) can be stored until the expiration date labeled on the box.

7. Precautions

1) It can only be used for *in vitro* diagnostic.
2) Avoid using expired reagents.
3) When the temperature is below 20°C, place the Auto plates in an oven (preheated 42~60°C) 5 to 10 minutes.
4) Avoid vigorous shaking, in order to avoid excessive formation of foam.
5) Carefully remove aluminum foil to avoid splashing.
6) Do not expose the opened reagents or Auto Plates to air. The evaporation would lead to pH change, or effect on the extraction effectiveness.
7) Please check the integrity of the Auto Plates and remember to mount the spin tips into the appropriate position of the suitable instrument before operating them.
8) Please wear a mask and disposable gloves when handling.
9) Use sterile consumables to avoid nuclease contamination.
10) Reagent solution contains guanidine salt, avoid using bleach containing detergent.
11) Avoid eyes, skin, and clothing contact with reagents. In case of any contact, flush with flowing water.
12) If any serious incident occurs, please report to the manufacturer and the competent authority of the member state in which the user and / or the patient is established.
13) The reagents are all colorless and transparent. Colored reagents indicate contamination, please replace it with a fresh plate before proceeding.

8. Materials required, Not Supplied

1) TANBead® Nucleic Acid Extraction System
   Model: Maelstrom 8 series and Maelstrom 4800 series (non-sterile)
2) Disposable gloves
3) Scissors, utility knives
4) Micropipette, disposable tips (10 µL / 200 µL / 1000 µL)
5) 1.5 mL microcentrifuge tube
6) 1~2 mm glass beads

9. Sample Collection, Transportation, and Storage

■ **Sample collection and storage**

1) Fungi samples can be stored at
   a. RT for 12 hours.
   b. 2~8°C up to 7 days.
   c. - 80°C long-term preservation.

■ **Specimen transportation**

Transportation of fungi specimens should follow specific transportation related law and should be kept between 2~25°C during transportation.

10. Nucleic Acids Extraction Protocol

1) Harvest sample by centrifugation at 5000 rpm for 5 minutes, then discard the culture medium.
2) Add appropriate amount of **100 µL glass beads (1~2 mm)** and **800 µL Lysis Buffer** the microcentrifuge tube.
3) Grind the sample by bead homogenizer equipment for 5 min.
4) Incubation at **room temperature for 5~10 min** to precipitate beads and lysate.
5) Carefully remove the aluminum foil from Auto Plate.
6) Use micropipette to load **800 µL lysate** into column **#1 / #7** of Auto Plate.
7) Set up spin tips.
   Maelstrom 8 series: Handle to mount tips and make sure that there is no gap between the neck of the spin tips and the spin shaft.
   Maelstrom 4800 series: Go to Tip page and press the mount tips region.
8) Push Auto Plates completely to the bottom of the plate rack. Make sure that the chamfer of the plate is at the lower left.
9) Push strips completely to the bottom of strip rack frame.
10) Close the door panel.
11) Select the program
    Maelstrom 8 series: Press "**61F-1**" for input samples at column #1 or "**61F-7**" for input samples at column #7.
    Maelstrom 4800 series: Press "**61F**".
    The parameters are given in following section.
12) Once the program has ended, buzzer shall alarm. Take out Auto Plate carefully.
13) Use micropipette to transfer the purified nucleic acids from column **#6 / #12** of Auto Plate to a clean tube.
14) Put the used 96 well plates and strips into the waste recovery can.
15) Discard used Auto Plate and strips into the waste recycling bin.

11. Program

■ **Maelstrom 8 series**

Program Name: 61F-1 / 7							
Well	1 / 7	2 / 8	3 / 9	4 / 10	5 / 11	6 / 12	
Volume	800 (μl)	800 (μl)	800 (μl)	800 (μl)	800 (μl)	130 (μl)	
Step	Well	Action	RPM	Time (Second)	CW/CCW (Second)	Temp.	Temp. Control
1	3 / 9	Mixing	3000	60	0	55	Yes
2	3 / 9	Collection	0	30	0	55	Yes
3	2 / 8	Mixing	3000	60	0	55	Yes
4	2 / 8	Collection	0	30	0	55	Yes
5	1 / 7	Mixing	3000	600	0	55	Yes
6	1 / 7	Collection	0	30	0	55	Yes
7	2 / 8	Mixing	3000	120	0	45	Yes
8	2 / 8	Collection	0	30	0	45	Yes
9	3 / 9	Mixing	3000	120	0	45	Yes
10	3 / 9	Collection	0	30	0	45	Yes
11	4 / 10	Mixing	3000	120	0	45	Yes
12	4 / 10	Collection	0	30	0	45	Yes
13	5 / 11	Mixing	3000	120	0	45	Yes
14	5 / 11	Collection	0	30	0	45	Yes
15	5 / 11	Vapor	0	300	0	45	Yes
16	6 / 12	Mixing	2700	600	0	45	Yes
17	6 / 12	Collection	0	60	0	45	Yes
18	6 / 12	Collection	0	60	0	45	Yes
19	5 / 11	Mixing	3000	60	0	0	No

■ **Maelstrom 4800 series**

Program Name: 61F				Model: Maelstrom 4800 series			
Temp1	Temp2						
40	40						
Well	Name	Volume	Action	Mixing	Collect		
1 / 7	LB	800	For.	Low	Low		
2 / 8	WB1	800	For	Low	Low		
3 / 9	MB	800	For	Low	Low		
4 / 10	WB2	800	For	Low	Low		
5 / 11	WB2	800	For	Low	Low		
6 / 12	EB	130	For	Low	Low		
Step	Well	Temp (°C)	Mixing (M)	Mixing Speed (RPM)	Collect (M)	Vapor (M)	Pause
1	3	-	0.5	3000	0.5	0	Off
2	2	-	1	3000	0.5	0	Off
3	1	55	10	3000	0.5	0	Off
4	2	-	2	3000	0.5	0	Off
5	3	-	2	3000	0.5	0	Off
6	4	-	2	3000	0.5	0	Off
7	5	-	2	3000	0.5	5	Off
8	6	45	10	2700	1	0	Off
9	6	45	0	3000	1	0	Off
10	5	-	1	3000	0	0	Off
11	3	-	0.5	3000	0.5	0	Off

12. Reagent performance

■ **Repeatability**

Under repeatability conditions where nucleic acids are extracted with the same reagent kit on the same source samples by the same operator. The coefficient of variation of nucleic acid extraction concentration is less than 5%.

■ **Reproducibility**

A five-day reproducibility test was carried out with the same source samples for 5 consecutive days with the same reagent kit by different operators. The coefficient of variation of nucleic acid extraction concentration is less than 5%.

■ **The stability of extracted DNA**

Storage Conditions	DNA stability
-80°C	Over 90 days
-20°C	28 days
4°C	14 days
25°C	2 days
Freeze-thaw	10 times

13. Explanation of Symbols

	Manufacturer		**Consult instructions for use**
	Temperature limit		**Contains sufficient for test**
CE	**CE mark**	IVD	***In vitro* diagnostic medical use**
REF	**Catalogue number**		**Caution**
LOT	**Batch code**	NON STERILE	**Non-sterile**
	Do not re-use		**Keep away from sunlight**
	Date of manufacture		**Use-by date**

EC REP

mdi Europa GmbH, Langenhagener Str. 71, 30855 Langenhagen, Germany

14. Post-market surveillance conclusion

After a risk assessment and clinical evaluation assessment, when weighing the benefits of medical device, patients, and the risks associated with the use of the device, the risk is acceptable. The post-market surveillance report shows that no death or serious adverse events occurred.